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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,664	06/18/2001	Shozo Koyama	AMN-003-002	7632

20374 7590 08/26/2003

KUBOVCIK & KUBOVCIK
SUITE 710
900 17TH STREET NW
WASHINGTON, DC 20006

EXAMINER
CEPERLEY, MARY

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/26/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

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Commissioner for Patents

See the attached letter.

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit: 1641

1) The preliminary amendment filed August 16, 2001 states that the instant application is a continuation of application serial no. 09/355,642. However, changes appear to have been made to the instant specification so that it is not *verbatim* the same as the specification of serial no. 09/355,642. In view of the changes made to the specification, clarification of the status of this application relative to application serial no. 09/355,642 is required.

2) The objection to the disclosure set forth below appears in a letter from the USPTO mailed October 08, 1999 in the parent application serial no. 09/355,642. ***The noted problems were not addressed in the parent application and have not been addressed in any preliminary amendment filed in the instant application.***

3) The disclosure is objected to under 37 CFR 1.71, as being so incomprehensible as to preclude a reasonable search of the prior art by the examiner. The following items are a few ***examples*** of the incomprehensible subject matter which is present in the specification and claims.

a) The overall translation from the Japanese priority document is so poor as to render the invention incomprehensible. For example, see page 11, lines 14-20:

> "It is not sufficient to accept a conventional idiotyped vaccine and/or antibody at the present, although it has been indicated that as a scientific knowledge multidimensional structure of biological substance mentioned above is important to generate various biological functions, and that as an acceptable proposal idiotype vaccine and/or antibody being applied structural diversity on the basis of species-differented (sic) cellular specificity in order to be induced functional diversity by multidimensional structure is logical."

b) The claims are directed to "an antigenic substance inducer". However, it is totally unclear as to what is meant by this term. Is this a substance which is antigenic in nature and which is used to induce the production of antibodies? What is a "substance inducer"? Is this "antigen substance inducer" a hapten which must be made antigenic by the attachment of an

immunogenic carrier? If this "substance" is a hapten or antigen, what specific epitope is the corresponding antibody reactive with?

c) In claim 1, (iv), what is the structure resulting from "R5 and R6 may form a ring by binding with another *condensation polycyclic hydrocarbon compound or heterocyclic compound*"? In claim 2, what is meant by the terms "pentacene", "hexacene", etc.

d) Why are the structures of claims 1, 3, 5, 7, and 10 separately defined? Do they have separate functions?

e) What subject matter is claim 18 meant to include? Is this a claim to an antibody? Are the "macromolecules" additional components which are present in a composition of some sort?

f) The actual subject encompassed by each of the individual claims is so completely unclear that no meaningful search of the claims can be made. See the following examples:

i) See paragraph ***b)*** above.

ii) What is meant by the term "a vaccine precursor or vaccine" of claim 12? How is the "precursor" or "vaccine" produced (product by process claim)? Is the "substance" of claim 1 (used in claim 12) antigenic *per se*, or must it be attached to an immunogenic carrier to be used to produce an antibody? Is the "vaccine precursor or vaccine" of claim 12 an antigen or an antibody produced from an antigen? These problems/questions also apply to product by process claims 13 and 14.

iii) How is the "idiotype antibody" of claim 15 different from the antibody of claim 13? Is an "anti-idiotype" antibody intended in claim 15? Where is this supported in the specification?

iv) Claim 17 recites an "antitoxin" or "antibody" manufactured using the "idiotype antibody inducer according to claim 15". However, claim 15 contains no reference to any "idiotype antibody inducer".

v) It is unclear whether claims 18-23 are intended to be product or method of use claims.

vi) Claim 18 recites "the vaccine precursor, vaccine, antibody, neutralizing antibody, antitoxin, idiotype antibody or anti-idiotype antibody induced by the idiotype antibody according to claim 12"; however, there is antecedent basis in claim 12 only for "a vaccine precursor or vaccine". See also, claims 19-22.

vii) It is completely unclear what is meant by the language of claim 24 "which is a labeled compound that has a labeled substance or that has substrate including compounds being capable to demonstrate effector sites". See also, the similar language of claims 25-28. Are the additional limitations meant to be method of use limitations or are they recitations of additional components present in some sort of composition?

4) Applicant is required to submit an amendment which clarifies the disclosure and claims so that the examiner may make a proper comparison of the invention with the prior art. Applicant should be careful not to introduce any new matter into the disclosure (i.e., subject matter which is not supported by the originally filed disclosure).

5) Applicant is advised that upon clarification and/or appropriate amendment of the claims, the claims may be subject to restriction, for example, among haptens (compounds); antigens (haptens attached to immunogenic carriers); antibodies; anti-idiotypic antibodies; methods of use of each of the haptens, antigens, antibodies and anti-idiotypic antibodies; and vaccine compositions (restrictable base on whether they contain the antigen or the antibody).

6) A shortened statutory period for reply to this action is set to expire thirty days or ONE MONTH, whichever is longer, from the mailing date of this letter.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 308-4556. The fax phone number for responses to be filed AFTER final rejection is (703) 305-3592.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

August 22, 2003

Mary E. (Molly) Ceperley
Primary Examiner
Art Unit 1641